is in descending order of predominance, or a list of all active ingredients and any inactive ingredients previously disclosed to the public as defined in §20.81 contained in a drug, or a list of all ingredients or components in a device. A particular ingredient or component or group of ingredients or components shall be deleted from any such list for a cosmetic or device prior to public disclosure upon a determination made pursuant to §20.44 that the ingredient or ingredients fall within the exemption established in §20.61 for trade secrets and confidential commercial information, and a notation shall be made that any such ingredient list is incomplete.

(5) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in §20.61.

(d) The following data and information submitted voluntarily to the Food and Drug Administration are not available for public disclosure unless they have been previously disclosed to the public as defined in §20.81 or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in §20.61:

(1) All safety, effectiveness, and functionality data and information for a developmental ingredient or product that has not previously been disclosed to the public as defined in §20.81.

(2) Manufacturing methods or processes, including quality control procedures.

(3) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(4) Quantitative or semiquantitative formulas.

(e) For purposes of this regulation, safety, effectiveness, and functionality data include all studies and tests of an ingredient or a product on animals and humans and all studies and tests on the ingredient or product for identity, stability, purity, potency, bioavailability, performance, and usefulness.

§20.112 Voluntary drug experience reports submitted by physicians and hospitals.

(a) A voluntary drug experience report to the Food and Drug Administration on FDA Form 3500 shall be handled in accordance with the rules established in §20.111(c)(3)(iii).

(b) If a person requests a copy of any such record relating to a specific individual or a specific incident, such request will be denied unless accompanied by the written consent to such disclosure of the person who submitted the report to the Food and Drug Administration and the individual who is the subject of the report.

[42 FR 15616, Mar. 22, 1977, as amended at 54 FR 9038, Mar. 3, 1989; 62 FR 52249, Oct. 7, 1997]

EFFECTIVE DATE NOTE: At 62 FR 52249, Oct. 7, 1997, in §20.112, paragraph (a) was amended by removing the words ''Form FDA–1639'' and inserting in their place the words ''FDA Form 3500'', effective Apr. 6, 1998.

§20.113 Voluntary product defect reports.

Voluntary reports of defects in products subject to the jurisdiction of the Food and Drug Administration are available for public disclosure:

(a) If the report is submitted by the manufacturer, after deletion of data and information falling within the exemptions established in §20.61 for trade secrets and confidential commercial or financial information and in §20.63 for personal privacy.

(b) If the report is submitted by any person other than the manufacturer, after deletion of names and other information that would identify the person submitting the report and any data or information falling within the exemption established in §20.63 for personal privacy.

§20.114 Data and information submitted pursuant to cooperative quality assurance agreements.

Data and information submitted to the Food and Drug Administration pursuant to a cooperative quality assurance agreement shall be handled in accordance with the rules established in §20.111.